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10/564,674	07/14/2006	Marcel Wijlaars	0470-060131	1707

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,674	WIJLAARS ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference).

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. (previously cited) in view of Slivka et al. (previously cited), Pissis et al. (previously cited) and Young et al. (previously cited).

Malmonge et al. teach a copolymer of 2-hydroxyethyl methacrylate (HEMA) and acrylic acid (AA) as artificial articular cartilage in a joint prosthesis (see page 175 column 1 paragraph 2-3; instant claims 8, 9, and 14). They go on to teach that the hydrogels made of this material have negative (ionized) groups fixed within the macromolecular network that are believed to participate in the compressive strength of the material (see page 174 column 2 paragraph 1 line15-page 175 column 1 line 5 and page 175 column 1 paragraphs 2-3; instant claim 8). Ionized groups were therefore added to the hydrogel prior to polymerization and were present after polymerization (see page 176 column 1 paragraph 1; instant claim 8). Malmonge et al. also teach the ratio of HEMA to AA in the polymer to be 97.5 to 2.5 as well as 95 to 5 (see page 175 column 1 paragraph 4; instant claim 8). Malmonge et al. do not teach whether this ratio is based upon mass or moles. In the case where the ratio described the molar balance,

the corresponding mass percentage of AA in the polymer would be 1.8% (mass percentage corresponding to 2.5 mol%) and 3.6% (mass percentage corresponding to 5 mol%), as calculated by the examiner. Further, Malmonge et al. also teach the hydrogel being soaked (saturated) in a liquid solution (see figure 1 and caption; instant claim 12). Malmonge et al. do not teach the incorporation of fibers into the taught hydrogel.

Slivka et al. teach a fiber reinforced gel structure for articular cartilage repair. Other known repair materials are taught to frequently lack mechanical properties to ensure long term efficacy and could lead to inadequate support during healing (see page 767 paragraph 1). Specifically, Slivka et al. teach that a polymer solution is combined with polymer fibers sized at 2.5 mm in length such that a gel was formed (see page 770 paragraph 1). The fibers are taught to be present at 5%, 10%, 15%, and 20% (see figure 2). As the fiber loading increased, the compressive modulus and yield strength increased, indicating an improvement in mechanical properties due to the presence of these fibers (see figure 7). In addition, Slivka et al. point to the 10% fiber loading as particularly good for its slightly higher stiffness as compared to native tissue (see page 778 paragraph 1).

Pissis et al. teach the incorporation of Nylon particles (fibers), a swellable polyurethane, into a poly(hydroxylethyl acrylate) hydrogel (see page 561 paragraph 1; instant claims 8 and 13). Pissis et al. also teach that all polymer hydrogels would benefit from having their mechanical properties improved and that the inclusion of the Nylon serves this purpose (see page 561 paragraph 1; instant claims 8 and 13). Further Pissis

et al. teach the inclusion of the Nylon particles at 10% (see page 561 paragraph 2 lines 17-18; instant claims 8 and 13).

Young et al. teach a fiber reinforced polyHEMA as a biomaterial (see abstract and page 1745 column 2 lines 6-13). Specifically Young et al. teach that due to the capability of hydrogels to absorb large amounts of water, their polymer networks and mechanical strength can be compromised in the process (see page 1745 column 1 lines 7). Young et al. go on to teach fiber reinforcement, the inclusion of fibrous material within the hydrogel, to improve the mechanical properties of these otherwise very versatile materials (see page 1745 column 1 line18-column 2 line 5). Further, Young et al. teach a nylon and elastic spandex fiber mesh as one utilized fiber reinforcement (see page 1746 column 1 lines 10-14 and figure 2). As demonstrated by the microscopic images provided, the fibers in this mesh were longer than one millimeter (see figure 2 panel c and panel d); instant claim 8)

Slivka et al. explicitly teach the inclusion of polymer fibers of at least one millimeter in length at 10% to 70% in a gel construct to improve its mechanical properties, which like Malmonge et al., is intended for articular cartilage repair. Therefore one of ordinary skill in the art would have been motivated to apply the same approach to improve the gel of Malmonge et al. since it also requires mechanical strength and integrity to function for its intended purpose as articular cartilage. Since both Pissis et al. and Young et al. teach fiber reinforcement in hydroxylated acrylate based hydrogel medical devices and Young et al. specifically teach their ability to mechanically reinforce such structures, it would have been obvious to one of ordinary

skill in the art at the time of the invention to embed a fiber mesh, as taught by Young et al., in the HEMA—AA hydrogel prosthesis of Malmonge et al. Further, since both Slivka et al. and Pissis et al. provide a known proportion of gel to mesh in such devices and Young et al. provide known varieties and dimensions of mesh used to reinforce hydrogels in biomaterials, one of ordinary skill would have also found it obvious to embed nylon/spandex fibers longer than one millimeter and composing approximately 10% of the hydrogel composite in the hydrogel composition of Malmonge et al. (applying a known technique to a known device ready for improvement to yield a predictable result/ use of known technique to improve similar devices in the same way). Consequently, the saturation of the Slivka et al., Pissis et al., and Young et al. modified gel of Malmonge et al. would also have the swellable nylon/spandex fibers saturated as well (see Malmonge et al. figure 1 and caption; instant claim 12).

Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. are silent in regards to the spandex fibers "sucking up" monomer solution. Two methodologies of preparing fiber reinforced gels are presented by the cited references, one of which is set forth for hydrogels in particular. Young et al. and Pissis et al. both teach the preparation of their composite hydrogels by the combination of reinforcing fibers/particles along with monomer solutions that include cross-linker and initiator followed by polymerization of the monomer to yield the final fiber reinforced hydrogel. Since urethane and carboxyl chemical groups are well known to form hydrogen bonds, one of ordinary skill in the art would reasonably expect such an association to occur in the unpolymerized mixture of HEMA, AA, and spandex fibers made obvious by the Malmonge et al. in view of Slivka

et al., Pissis et al., and Young et al. This association can be termed “sucking up” of the acrylic acid monomer solution (see instant claims 8 and 15). Moreover, applicants exemplify spandex fibers, specifically, as the envisioned polyurethane reinforcing fiber that has this property of “sucking up” monomer solutions of HEMA and/or sodium methacrylate upon immersion (see instant specification page 1 lines 18-21, page 2 lines 1-2 and page 3 lines 1-3). Thus the fiber-reinforced matrix as claimed composed of HEMA-AA with spandex fibers made obvious by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. would also include a monomer solution "sucked up” by the fibers. Therefore claims 8-9 and 12-15 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al.

Claims 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. as applied to claims 8-9 and 12-15 above, and further in view of Kou et al. (previously cited).

The teachings of Malmonge et al. in view of Slivka et al., Pissis et al. and Young et al. make obvious a HEMA-AA hydrogel with 10% Nylon/spandex fibers (dry weight), such that the AA content was from 1-5% (dry weight). However, this modified reference does not teach the use of methacrylic acid (MA) in the hydrogel.

Kou et al. teach a HEMA-MA hydrogel as being known in the art at the time of invention (see page 241 column 1 paragraph 1; instant claims 8 and 10). Further, the MA only differs from the AA in that it has an additional methyl group in the place of a hydrogen atom. Thus in a hydrogel, HEMA-MA would have negative groups fixed within

its macromolecular network like HEMA-AA. "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups)are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601(CCPA 1978) (stereoisomers prima facie obvious)." In addition, the MPEP cites Deuel, 51 F.3d at1558, 34 USPQ2d at 1214 and states that, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." (see MPEP 2144.08). It would therefore be obvious to one of ordinary skill in the art at the time the invention was made to employ HEMA-MA in place of the HEMAA-AA taught by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. It also would have been obvious for one of ordinary skill in the art to pursue known options within their technical grasp and use HEMA-MA instead of HEMA-AA in the Slivka et al., Pissis et al., and Young et al. modified hydrogel of Malmonge et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the monomer ratios taught by Malmonge et al. where MA replaces AA. Therefore claims 8 and 10 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., Young et al., and Kou et al.

Response to Arguments

Applicants' arguments and declaration, filed November 18, 2009, have been fully considered but they are not deemed to be persuasive.

Applicants argue that there is no teaching, suggestion, or motivation provided to combine the cited references. As applicants also note in their arguments, this is not the only basis upon which an obviousness rejection is predicated. In addition, the use of known technique to improve similar devices (methods or products) in the same way is also a suitable rationale and is the primary one upon which the rejection was based. Nevertheless, there was, in addition, ample suggestion from the prior art references and the knowledge generally available to one of ordinary skill in the art to modify Malmonge et al. It was well established in the prior art that hydrogels intended for use as surgical implants have been reinforced with fiber additives to improve their mechanical properties. Mansmann (see IDS) provide brief a review and listing of references detailing such uses and reinforcement approaches (see paragraphs 14 and 15). In addition, Pissis et al, Slivka et al., and Young et al. all teach that the incorporation of fibers into a gel or hydrogel improves its mechanical properties. So in addition, to the knowledge held by the ordinary artisan, the cited prior art also motivates the incorporation of fibers into a hydrogel to improve its mechanical properties. Malmonge et al. teach a polyHEMA based hydrogel intended for use as cartilage, a load bearing *in vivo* application where mechanical integrity is very important. Based upon knowledge generally held by one of ordinary skill in the art, there was a motivation to incorporate fiber reinforcement into this gel because they were known to improve the mechanical

properties of such gels for this intended use. Since this approach has been well established, one of ordinary skill in the art has good reason to look to any reference that applies such a structural reinforcement approach in implants, in general, and in hydrogels (composed of materials suitable for implantation) in particular, for guidance on suitable fiber materials and constituent proportions (e.g. the question remains: what materials should be used and how much should be incorporated?). Slivka et al. then demonstrates that in gels intended for cartilage repair, the inclusion of fibers improves the compressive strength of the material. However, their fibers are biodegradable, while the matrix of Malmonge et al. is not. Degradation of the reinforcing material in a gel of Malmonge et al. would not be desirable, but the implications of Slivka et al. (e.g. effectiveness of fiber reinforcement in cartilage repair/replacement materials) are still important and more broadly applicable to the system of Malmonge et al. Pissis et al. teaches non-degradable fibers/particles used to reinforce a poly(hydroyethylacrylate) hydrogel and draw a parallel between the properties of this hydrogel and polyHEMA. While Pissis et al. do not intend their hydrogel for cartilage applications, in particular, or teach the resulting mechanical properties of the reinforced gel, they do teach a polymer in the same class as that utilized by Malmonge et al. and establish that such polymers had been fiber reinforced with nylon. Young et al. then teaches fiber reinforced hydrogels for *in vivo* use where the inclusion of spandex and nylon fibers improves the elasticity of polyHEMA hydrogels. Thus polyHEMA hydrogels reinforced with nylon and spandex fibers were known to be suitable for *in vivo* use and have improved mechanical properties over their unreinforced counterparts. Elasticity along with compressive

strength are important mechanical properties in cartilage and this collection of references demonstrate that the inclusion of fiber reinforcement in gels improves both of these properties. Moreover, these references teach the types, proportions, sizes, and architecture of fibers that were known to provide this type of reinforcement, and establish that polyHEMA hydrogels intended for *in vivo* use and implantation, like that of Malmonge et al., were known to be mechanically improved by the inclusion of these fibers in their structure. One of ordinary skill in the art would certainly be capable of assimilating the information in these references along with the required dimensions of the end product, to construct a fiber reinforced material as claimed that is suitable for use as a cartilage-like material.

Contrary to applicants' arguments, it is not necessary that each secondary reference individually remedy all the deficiencies of the primary reference in order for the secondary references to still collectively fill the void left by the primary reference. Thus Kou et al. is not required to teach a fiber-reinforced hydrogel with 10-70% fibers that are greater than one millimeter in length in order to still contribute to the teachings of Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. In addition, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006) (see MPEP 2144 IV).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

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